

R E M A R K S

Claims 1 and 3-25 are pending in the present application. No new matter has been added by way of the present amendment. For instance, the subject matter of claim 2 has been amended into claim 1. Parallel amendments have been made to dependent claim 5. Also, due to the cancellation of claim 2, the dependency of claims 3, 6, 10, 20 and 23 have been amended. Additionally, the specification has been amended to correct inadvertent typographical errors. For instance, the amendment at page 9, line 18, which changed "target" protein to read "targeting" protein is supported by, for instance, page 9, line 12 of the specification. At page 20, line 20, the recitation of "10 mg" was corrected to "10 ml". This is supported by the fact that this is a liquid measurement in a 10 ml graduated tube. Page 21, line 30 was amended such that V_B and V_T correctly corresponded to the volume of the "top phase" and volume of the "bottom phase". The amendment at page 29, line 7 correctly references EGIcore-HFBI fusion as supported by Example 16, in particular, page 29, line 16. Lastly, the amendment to page 45, line 23 is supported by Example 38, in particular, page 45, line 21 and page 45, line 32. Accordingly, no new matter has been added.

In view of the following remarks, the Examiner is requested to reconsider the outstanding Unity of Invention Requirement.

In the outstanding objection, the Examiner has required Applicants to elect one of the following four groups:

Group I, claims 1-5, 10-15 and 18-23, drawn to a method of partitioning of a substance in aqueous two-phase system and a method of separating hydrophobins or hydrophobin-like proteins in aqueous two-phase system, and a process of producing a fusion protein comprising a hydrophobin or hydrophobin-like proteins.

Group II, claims 1-9, 15, 20-23, drawn to a method of partitioning of a substance in aqueous two-phase system and a method of separating hydrophobins or hydrophobin-like proteins in aqueous two-phase system comprising combining of cells of interest to a target protein comprises interaction of said protein with the surface of said cells.

Group III, claims 16-17, drawn to a recombinant organism producing the fusion protein of Group 2.

Group IV, claim 24, drawn to a method of separating hydrophobins in aqueous two-phase system.

Additionally, the Examiner has made an "Additional election", which states that regardless of the elected group, Applicant is required to elect a single disclosed composition to which claims are restricted. Moreover, the Examiner asserts that if Group I is elected, "applicant is required to elect an enzyme from claim 10, because protease hydrolyse peptide bond, cellulase catalyses hydrolysis of cellulose whereas hemicellulase degrades hemicellulose to galactose; thus, these enzymes are structurally and functionally distinct/different from one another."

Applicants respectfully traverse the Examiner's outstanding rejection. The separation of claims 1-24 into separate groups is improper. The present application is a national phase of PCT/FI00/00249, as such unity of invention standards apply.

As explained in MPEP 1893.03(d), the principles of unity of invention as used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that Applicant would have a right to include in a single application

all of those inventions, which are so linked as to form a single general inventive concept.

A group of inventions is considered linked to form a single general inventive concept, whether it is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression "special technical feature" is defined as meaning those technical features that define the contribution, which each claimed invention, considered as a whole, makes over the prior art.

The Examiner is apparently of the opinion that the subject matter of claim 24 defines a special technical feature of all other claims. For instance, the Examiner has cited U.S. Patent No. 5,882,520 as support that this feature is known in the art. Applicants disagree with the Examiner's characterization of the present invention.

The special technical feature linking all of the claims of the present invention is the exploitation of the specific characteristics of hydrophobins or hydrophobin-like proteins in aqueous two-phase systems. Applicants submit that the finding

that hydrophobins are easily separable in ATPS, and that they may therefore be used to form amphiphatic fusion proteins easily separable in said system, is novel. Consequently, Applicants submit that all of the claims are based on a single inventive concept, and that the unity of the invention should be acknowledged.

Richards et al. (U.S. Patent 5,582,520) and the present invention both disclose an aqueous two-phase system for portioning biological molecules. However, the gist of the cited reference is the exploitation of the characteristics of arabino-galactan to facilitate the separation by acting as a basic component in the ATPS system, whereas the gist of the present invention is the exploitation of the characteristics of hydrophobins to modify the characteristics of the target protein and thus facilitating the separation of the target protein. Claim 24 of the present application defines a specific embodiment, in which the hydrophobins as such are the target proteins, but at the same time the targeting proteins, whereas in claim 1 hydrophobins are targeting proteins for other (target) proteins to be separated.

Different aqueous two-phase systems have long been used for separation of biological molecules, as is also discussed in the present application (see "Background of the Invention").

Applicants also state on page 9, line 24: "Several ATPS systems are suitable for performing this invention." The present method is thus not directed to an ATPS system as such, which is prior known, but a specific application of such a system, in which hydrophobins are used as a targeting protein. Therefore, Applicants submit that the application does not include distinct inventions, for which separate searches would be necessary.

Accordingly, Applicants submit that the invention listed in Groups I-IV above do relate to a single inventive concept under PCT Rule 13.1. Moreover, the Examiner has incorrectly characterized the prior art, thus, the "special technical feature", according to the present invention, does represent a contribution over the art. Thus, PCT Rule 13.2 is satisfied. Accordingly, the holding of lack of unity of invention is improper and should be withdrawn.

Additionally, the Examiner's "Additional election" and improperly defined restriction at the bottom of page 2 and the

top of page 3 of the outstanding Office Action are procedurally incorrect. If the Examiner wishes to make election of species, a request for election of species should be set forth. However, it appears as though the Examiner is requesting that Applicants make an "election" within an elected group. As such, this would constitute an additional restriction requirement, not a request for election of species. This is procedurally incorrect. If the Examiner wishes to restrict the groups further, the Examiner should identify the groups individually, indicating that they are patentably distinct. This has not been done.

Accordingly, Applicants submit that the Examiner has failed to shift the burden to Applicants to make an additional election. Moreover, the Examiner's requirement that, for instance, Applicants elect an enzyme from claim 10 (presumably the Examiner is referring to claim 13), is unnecessary. The fact that the enzymes listed in claim 13 may be structurally and functionally different has nothing to do with the present invention. Applicants have demonstrated in the examples that the present method can be applied to various proteins (see also page 6, third paragraph of the present specification).

Therefore, Applicants submit that they are entitled to claim 13 as a single invention.

In view of the above, Applicants maintain the strong traversal of the outstanding restriction requirement. However, in order to be fully responsive, Applicants hereby elect Group I. This is an election with traverse.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Craig A. McRobbie (Reg. No. 42,874) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.


Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a two (2) month extension of time for filing a reply in connection with the present application, and the required fee of \$420.00 is attached hereto.

Appl. No. 09/936,823

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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